REMARKS

In response to the above Office Action, claims 1, 4, 7-10, 12-14, 20, 23-26 and 29-31 have been cancelled and rewritten as new claims 32-48 to place them in a more convenient order.

New main claim 32 corresponds to former claim 1 and has been rewritten as suggested by the Examiner. The claim also now includes the limitation that the preparation is in the form of a powder, a granule, a pill, a tablet, or a capsule. In other words, in a solid form. Support for this can be found, for example, on page 12, line 23 to page 13, line 1. Claim 21 has not been retained in the new claims. Accordingly, it is believed all of the Examiner's objections, as set forth on page 2 of the Office Action, have been met.

With respect to the rejections of claims 29, 30, 31, now claims 34, 35, and 40, under 35 U.S.C. §112, second paragraph, the new claims do not contain the term "essentially."

With respect to the rejection of claim 25, now claim 47, under 35 U.S.C. §112, second paragraph, this claim has been amended to make it clear that the granules contain "the" cilostazol preparation of claim 44 (formerly claim 20) from which the claim depends. As set forth in the claims, the granules contain not only this cilostazol preparation, but also "rapid release powders or tablets containing cilostazol." In other words, these rapid release powders or tablets containing cilostazol are in addition to the cilostazol preparation. Thus, just because these powders or tablets are rapid release, does not make the claim inconsistent with the sustained release cilostazol preparation.

A similar amendment changing "a" cilostazol preparation to "the" cilostazol preparation has also been made to claims 23, 24, and 26, now claims 45, 46, and 48, respectively.

Finally, with respect to the rejection of claim 26, now claim 48, under 35 U.S.C. §112, second paragraph, "type" and "small" have been deleted and the claim has been rewritten for clarity.

It is believed all of the claims comply with the requirements of §112, and its withdrawal as a ground of rejection of the claims is therefore requested.

In the Office Action, the Examiner rejected claims 1, 4, 7-10, 12-14, and 29-31, now claims 32-43, under 35 U.S.C. §103(a) for being obvious over Fujimura et al. (hereafter Fujimura) in view of Wood et al. (hereafter Wood). The indicated allowance of claims 20 and 23-26, now claims 44-48, is appreciated. However, it is believed claims 32-43 are also allowable for the following reasons.

Fujimura discloses the bronchoprotective effect of cilostazol. The Examiner points out that "The powder is sized for intrabronchial administration, i.e., [that it] has an extremely small particle size on the order of about 3-4 microns. See the passage spanning the bottom righthand side of page 221 to the lefthand top side of page 222."

However, it is not seen where the Examiner found any description that "an extremely small particle size on the order of about 3-4 microns" of cilostazol was used to make the tested doses in Fujimura. Rather, beginning at the bottom of the righthand side of page 221, the reference simply describes "The PDE3 inhibitor, cilostazol, was intrabronchially administered in powder form via a spray (Otsuka Pharmaceutical Co., Japan)." Nothing is mentioned about the particle size of the powder.

In fact, Otsuka Pharmaceutical Co., Japan, the source of this powder in Fujimura, is the assignee of this application and they have confirmed that cilostazol powder having an average particle diameter of 3-4 microns was not distributed to the persons that conducted the tests set forth in Fujimura. Rather, a bulk cilostazol powder having an average particle diameter of about 20 μm (similar to that used in Comparative Examples 1 and 2 of the present specification), was provided to them. Thus the cilostazol of Fujimura may have been in the form of a "powder," but not a powder having an average particle diameter of 10 μm or less as claimed.

Moreover, in Fujimura, the cilostazol powder was diluted with lactate powder to make the tested doses for intrabronchial administration, but lactate powder is not a surfactant which is a part of the claimed cilostazol preparation.

Accordingly, it is submitted that Fujimura fails to teach two significant features of the invention as set forth in claim 32; namely, that the cilostazol is in the form of a fine powder having an average particle diameter of 10 μm or less and that it is incorporated into a surfactant.

Wood discloses an aerosol comprising droplets of an aqueous dispersion of nanoparticles, the nanoparticles comprising insoluble therapeutic or diagnostic agent particles having a surface modifier (e.g. a surfactant) on the surface thereof. The aqueous dispersion is subjected to nebulizing to form droplets having a diameter of less than 50 μm so as to be administrable to the respiratory system. Claim 1 of the reference teaches that the liquid droplets have a particle size of less than 10 microns in diameter.

The Examiner therefore believes it would have been obvious "to have treated the cilostazol powder of [Fujimura] with a surfactant such as lauryl sulfate . . . as taught by [Wood]. However, even if for the sake of argument this was true, the combination of references still does not teach or suggest that the cilostazol power has an average particle size of 10 μm.

As required by M.P.E.P. §2143, to establish a prima facie case of obviousness it is necessary for the references in combination to teach or suggest all of the claimed limitations. Since neither Fujimura nor Wood teach the claimed cilostazol powder, it is submitted the claims cannot be considered obvious over this combination of references.

Moreover, the composition of Wood is an aerosol in liquid form that is intended to be absorbed via the lungs and is not intended to reach the lower portion of the digestive tract as is applicants' composition. In contrast, in the present invention the cilostazol preparation is in a solid form, i.e., in the form of a powder, granule, pill, tablet or capsule which can be absorbed via the digestive tract after oral administration.

As noted, the cilostazol is a fine powder having an average particle diameter of 10 μm or less and it is incorporated into a surfactant as a dispersing and/or solubilizing agent, so that the cilostazol is capable of dissolving at the lower portion of a human digestive tract. The surfactant acts as a dispersing and/or solubilizing agent in the digestive liquids after taking the preparation orally. This is an entirely different type of composition than Wood's composition, and claim 32 has been amended to highlight this difference over Wood.

It is believed claims 32-48 define a patentable invention over Fujimura and Wood, and their withdrawal as a ground of rejection of the claims under §103 is therefore requested.

It is believed claims 32-48 are in condition for allowance.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 21, 2005

By: _____
Arthur S. Garrett
Reg. No. 20,338

937341_1